

REMARKS

This application has been carefully considered in light of the Final Office Action of February 12, 2003 and an Advisory Action issued by the Examiner on May 29, 2003. As a result, claim 1 has been further amended to specify that the prolonged local effect to which the present invention is directed is the effect on the skin of an individual, and further that it is a prolongation of the normal period of time that a pharmaceutically or cosmetically active substance exhibits which is prolonged or extended. In other words, pharmaceutically or cosmetically active substances which are topically applied for purposes of treating skin conditions exhibit a local effect for periods of time. The present invention is directed to the surprising discovery that when pharmaceutically or cosmetically active substances are added to an oil-in-water emulsion carrier which includes an oily non-polar lipid material, an aqueous phase and a galactolipid material as an emulsifier to form a topical formulation, and when the topical formulation is applied on a person's skin the local effect of the pharmaceutically or cosmetically active substance is prolonged or extended for a greater period of time than would normally be expected.

In the Advisory Action the Examiner stated that the local/prolonged effect on the outer skin is not recited in the rejected claims. In this respect, claim 1 has been amended such that it is believed that the local/prolonged effect on the outer skin is positively recited within the claim.

Additionally, the Examiner has pointed out that a specific time frame defining a prolonged effect is not recited in the claims. In this respect, claim 1 has been amended to recite that the pharmaceutically or cosmetically active substance normally exhibits a local effect on skin for a period of time and that the topical cream or lotion formulation defined by claim 1 results in a prolongation of the local effect beyond the period of time normally associated with the pharmaceutically or cosmetically active substance. It is believed that this reference provides a positive definition of "prolonged".

Claims 1-13 remain within the present application. These claims have been rejected under 35 U.S.C. § 103(a) as being obvious and therefore unpatentable over US Patent 6,068,860 when considered in view of the teachings of WO 95/20943. Claim 12 remains rejected over the primary two references when further considered in view of the further reference to US Patent

4,444,755.

Applicants reiterate their remarks raised in the response to the Final Office Action filed on May 12, 2003. Neither of the primary references relied upon teaches nor discloses that a pharmaceutically or cosmetically active compound which exhibits a local effect on skin for a period of time can be mixed with an oil-in-water emulsion utilizing a galactolipid emulsifier such that, when applied to the surface of skin, the local effect is prolonged relative to the normal period of time. US Patent 6,068,860 specifically teaches and is directed to pharmaceutical formulations which are prepared in order to promote rapid penetration of an active surface through layers of the skin so as to target a specific substance at a specific target site. It is respectfully submitted that rapid penetration and concentration of an active as taught in US Patent 6,068,860 would not teach one of ordinary skill in the art to prepare an oil-in-water emulsion carrier and mix it with a galactolipid material in order to extend a local effect of a pharmaceutically or cosmetically active substance which is added to the emulsion.

In this respect, the Examiner notes that Table 4 of the present application reflects that one condition being tested with

topical creams or lotions prepared in accordance with the present invention is whether or not they are easily absorbed into the skin. This question appears under the immediate reaction section of Table 4 of the present application. However, whether or not the cream or lotion prepared in accordance with the present invention is easily absorbed into the skin does not change the inventive thrust of the present invention which is directed to extending the local effect on the skin of an applied cream or lotion formulation prepared in accordance with the teachings of the present invention. The remainder of Table 4 is directed to reflecting the results as they relate to the feel, texture and appearance of creams and lotions at time periods after topical application extending to a period of two days. What the test reflects is the topical effect of the topical creams or lotions, prepared in accordance with the present invention, do provide a prolonged effect with respect to the active substances which are incorporated in such creams and lotions over the effect which would be normally anticipated using such active substances.

Concerning the last remarks appearing on Page 3 of the Advisory Action, applicants respectfully submit that the test results reflected in the present application, such as those which

were measured by determining the capacity on the skin surface as disclosed beginning at Page 15 of the present application, do provide specific test results which support the unexpectedness of the prolonged effect which is achieved utilizing the teachings of the present invention. It is respectfully submitted that it is not necessary to make a direct comparison with the prior art because the prior art does not teach nor disclose prolonging a topical effect of an active substance, as is taught by the present invention.

Concerning the reference to the WO Publication as well as the additional US reference, Patent 4,444,775, applicants reiterate the distinctions between those references and the present invention as outlined in the response to the Final Office Action which was filed May 12, 2003.

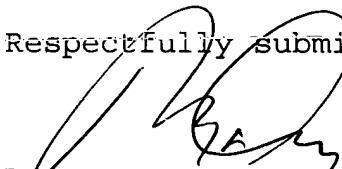
For the reasons set forth above and due to the further amendment to claim 1, it is respectfully submitted that this application is distinguishable with respect to the prior art taken alone or in combination and, therefore, reconsideration of the grounds for rejection is respectfully solicited and favorable consideration and allowance of claims 1-13 requested.

Should the Examiner have any further questions concerning

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the allowability of the claims, it is requested that a personal interview be granted with the undersigned attorney-of-record at the convenience of the Examiner. In view of this request, it would be appreciated if the Examiner would contact the undersigned attorney for purposes of scheduling such an interview to further expedite the prosecution of the application if there remains any further issues with regard to patentability.

Respectfully submitted,



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